



# NIES AT ITS BEST

Animal Products Permitting and Negotiation Services (APPNS)

December 2016 Quarterly Edition, Volume 1

## Our Mission

- To safeguard the health of domestic livestock and poultry by inspecting and /or quarantining animals and animal products to mitigate any animal disease risk through risk assessments and sound science
- To facilitate trade, promote safe movement, negotiate science-based import/export requirements, and collaborate with other agencies and departments to remove technical barriers to trade
- To serve as the preeminent resource for safeguarding the nation's food supply from agricultural biological select agents and toxins
- To cooperate and collaborate with international animal health standard setting organizations to develop science-based health measures for safe trade
- To utilize science-based performance measures and a focus on consistent, standard practices carried out by a responsive workforce



## Animal Product

Any material derived from the body of an animal. Examples are fat, meat, skin, organs, blood, milk, eggs, and lesser known products such as rennet, gelatin and rendered animal meals.



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[ASKNIES.Products@aphis.usda.gov](mailto:ASKNIES.Products@aphis.usda.gov) (Questions)  
**Fax:** (301) 734-8226  
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# HOT TOPICS

## Crossing the Canadian Border

Many stakeholders contact NIES to obtain information regarding the importation of Animal/Animal By-Products into the United States for personal consumption. Question such as: I am going on a camping trip, what meats are allowed to cross the boarder? Or, I am on a special diet, what food items can I bring into the US traveling from Canada? Below are the items that are allowed to cross the boarder coming from Canada for personal use.

In general, Canadian ruminant material (i.e., beef, camel, and cervid - **other than** sheep and goat) including milk and milk products, avian (poultry meat and eggs/egg products), porcine (pork) are enterable in passenger baggage.

Hunter-harvested game meat of bovine (e.g., cattle, bison), ovine (e.g., bighorn sheep, that is eviscerated with heads removed), porcine (e.g., wild boar), caprine (e.g., mountain goats, mountain sheep, musk ox that is eviscerated with heads removed), avian (e.g., ducks, geese) and cervid (e.g., caribou, deer, elk, moose) origin for the hunter's own personal use and accompanied by a valid hunting license or other appropriate documentation (proof of species and origin) are allowed in passenger baggage.

Personal-use amounts of equine meat or meat products commercially packaged and labeled are allowed in passenger baggage.

For more information on this topic, please contact 301-851-3300 option 1 for further assistance.

## Did you know.....

**O**megaven is an experimental fatty acid emulsion used to treat short bowel syndrome in infants and newborns with low birth weight.

Omegaven contains fish oil and egg lecithin which NIES no longer regulates.

Stakeholders can now contact the FDA regarding the importation of Omegaven.



# HOT TOPICS

## NIES New Lactose Regulations

### New Lactose Project Plan

#### What does the project entail and why is it important?

Section 94.16 of 9 CFR places restrictions on milk and milk products originating in, or shipped from, regions in which Foot and Mouth Disease (FMD) is considered to exist. Currently, products containing dried milk ingredients, including lactose, are allowed to enter the US from regions APHIS considers affected with Foot and Mouth Disease (FMD) under certain import requirements. .

VS has assessed the FMD risk of lactose and determined that it is not a viable vector for FMD or Rinderpest. Therefore, the risk of entry of FMD via products containing lactose is negligible.

#### What import commodities will be affected?

Products containing lactose in any amount that are for human or animal consumption, and are legally imported and meeting all import requirements for human or animal consumption as determined by the applicable regulatory agency.

These commodities may be imported under the newly created USDA Guideline for Importation #1107. This list is not all inclusive:

- Pharmaceuticals
- Nutraceuticals
- Dietary/nutritional supplements
- Culture media
- Medical devices
- Placebos
- Investigational Pharmaceuticals

More information about *Guideline 1107* can be found at the link below:

[https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/import-live-animals/ct\\_guidelines\\_for\\_importation\\_of\\_lactose\\_and\\_lactose\\_derivatives\\_1107](https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/import-live-animals/ct_guidelines_for_importation_of_lactose_and_lactose_derivatives_1107)

#### Who are the primary Stakeholders?

Primary stakeholders that would be impacted by this regulatory change include human and veterinary pharmaceutical companies, producers/manufacturers of products for animal consumption/animal feed, producers/manufacturers of food products for human consumption.

A USDA APHIS VS import permit (VS Form 16-6) will not be required for commodities for human and/or animal consumption or use if lactose or galactose or lactulose are the ONLY animal origin ingredient.

USDA, APHIS, VS recommends that the following documentation or information accompanies each shipment, and be presented for review by the Department of Homeland Security, Customs and Border Protection (CBP) Agriculture Specialists/Officers at the U.S. port of arrival.

- A document on company letterhead prepared by the producer/manufacturer, shipper, or seller identifying lactose or galactose or lactulose as the only animal origin ingredient; OR
- An official government certificate identifying lactose or galactose or lactulose as the only animal derived ingredient

If you have further questions about animal products and their eligibility for importation into the United States or their certification requirements, please contact **National Import Export Services at (301) 851-3300, option 1** or you can email us at: [AskNIES.Products@aphis.usda.gov](mailto:AskNIES.Products@aphis.usda.gov).



## Notice of Intent to Change Policy

The Animal and Plant Health Inspection Service, NIES, Animal Products Permitting and Negotiation Services Division, has a new upcoming policy change for the importation of bovine meat and meat products from Australia and New Zealand. When implemented, this policy will allow the use of a hard copy extract of the electronic certification data to take the place of the original, hard copy, wet signature certificate. The broker/importer would present CBP with the hard copy of the extract of the electronic certification data, while the electronic certification data that is reflected on computer extract is sent directly to FSIS. More information will be provided once this new policy is in place.

## USDA e-Authentication

**U**SDA e-Authentication is the system used by USDA agencies to enable customers to obtain accounts that will allow them to access USDA Web applications and services via the Internet. This includes things such as submitting forms electronically, completing surveys online, and checking the status of your USDA accounts.

Please note that USDA will only accept e-Authentication Accounts from individuals.

Currently USDA e-Authentication does not have the mechanism to issue accounts to businesses, corporations or other entities.

To apply for a USDA e-Authentication Account, please visit our website at [www.aphis.usda.gov](http://www.aphis.usda.gov)

## Do I need a permit?

NIES, Animal Products Permitting and Negotiation Services Division issues permits for animal origin material, however there are certain products that do not require a permit from our office. Please see list below (or visit our website) to see a list of materials that **do not require a USDA import permit, but will be reviewed at the port of entry.** <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information>

[1100](#) Human Pharmaceuticals and Human Vaccines Containing Animal Components

[1101](#) Non-Human Primate Material (excluding cell cultures)

[1102](#) Feline and Canine Material

[1103](#) Live Laboratory Mammals and Their Material (for research purposes)

[1104](#) Amphibians, Fish, Reptiles, Shellfish and Aquatic Species (includes venom) Revised June 2014

[1105](#) Chemically Synthesized Materials

[1107](#) Guidelines for Importation of Lactose and Lactose Derivatives

[1110](#) Microbially Produced Materials

[1114](#) Recombinant Microbes and Their Products

[1116](#) Non-Pathogenic Microorganisms (and their extracts)

[1119](#) PET CHEWS/TREATS made of ANTLERS or RAWHIDE

[1120](#) Cell Cultures/Lines, Recombinant Cell Cultures/Lines, and Their Products (for in vitro use)

[1121](#) Test Kits

[1122](#) Vitamins and Minerals

[1123](#) Histopathological Fixed Slides





**P**ayments for applications to import an animal/animal-byproducts into the United States are as follows:

Application	Fee
New Application	\$150
Renewal Application	\$97
On-Hold Applications	\$565
Amendments	\$75
Fetal Bovine Permits	\$512

\*\*All payment

for services

rendered are considered a processing fee

(non-refundable) and does not guarantee permit approval or shipment release\*\*



## APHIS/NIES/APPNS Email Communication Tool

- ♦ When sending permit applications and/or status requests for animal/animal by-products, please send those requests to [animalproducts.application@aphis.usda.gov](mailto:animalproducts.application@aphis.usda.gov) Please remember to include permit/application numbers when communicating with our office via email and/or phone. This will make the process go smoothly. We can be reached at 301-851-3300, Option 1 if you need further information about submitting applications electronically.
- ♦ When sending import questions for animal/animal by-products, please send those questions to [asknies.products@aphis.usda.gov](mailto:asknies.products@aphis.usda.gov) Your questions will be answered within 48 business hours.